PATENT
Attorney Docket **056707-5009-01**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Gregory M. Glenn *et al.***	)	
U.S. Application No. **10/633,626**	)	Group Art Unit: **1644**
Filed: **August 5, 2003**	)	Examiner: **Yunsoo Kim**
For: **Dry Formulation for Transcutaneous Immunization**	)	

Commissioner for Patents
U.S. Patent and Trademark Office
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Randolph Building
401 Dulany Street
Alexandria, VA 22314

DECLARATION UNDER 37 C.F.R. § 1.132

I, the undersigned, Diane Epperson, do hereby declare that:

1. I am a citizen of the United States, residing at 6501 Brookes Hill Ct., Bethesda, Maryland.

2. I have been awarded a doctorate in Immunology from Harvard University. I did my postdoctoral training in Immunology, Molecular Immunology and Cancer Immunotherapy at Yale University and the National Institutes of Health.

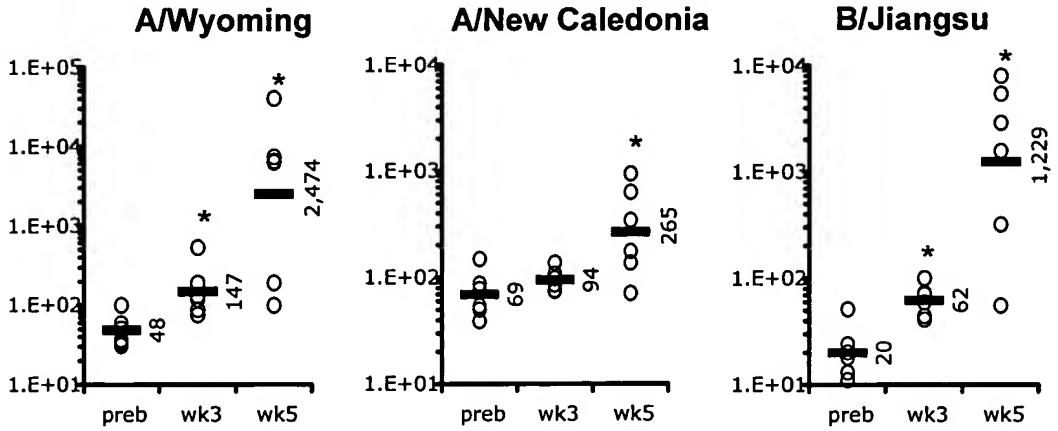
3. I have been employed by Iomai Corporation, since November, 2001 and I am presently the Manager of Pre-clinical Immunolgy at Iomai Corporation. During my employment at Iomai Corporation, I have been engaged in research and development in the area of skin immunization and cancer immunotherapy.

4. I am familiar with the specification and pending claims of U.S. Patent Application No. 10/633,626. I have reviewed the Office Action, mailed January 10, 2006. I believe that the specification enables the scope of the claims in view of the following experimental data performed at Iomai Corporation:

The experiment was established to investigate whether an antigen delivered by transcutaneous immunization in the absence of hydration or pretreatment of the skin can induce an immune response.

In this experiment guinea pigs were carefully shaved to expose the skin immediately before the addition of the patch. No skin manipulations were performed. There was no hydration or pretreatment of the skin. A dry formulated patch comprised of trivalent influenza split virus containing 15ug of hemagglutinin (5ug A/Wyoming strain, 5ug A/New Caledonia strain, and 5ug B/Jiangsu strain) was placed on the skin and worn overnight. The animals were given two immunizations via a patch. The first was at day 1 and the second on day 22.

The results of the experiment are shown in the following graphs. The results indicate that titers to the three influenza strains increased over the antibody titers before immunization.



Geomeans from each time point (n=6 animals) are signified by a bar and the given to the right of each bar. An * denotes titers that are statistically greater ($p<0.05$) than the pre-bleed titers from the same animals by two-tailed students T-test.

Titers to all three immunizing influenza strains rose above the titers in the same animals before immunization (pre-bleed). The week 3 titers reflect the immune response after one

immunization; the week 5 titers reflect the immune response after two immunizations. The titers rose after each immunization for each strain. The results establish that we can induce an immune response in animals by applying to their skin a dry formulation comprising immunizing antigens without hydrating or disrupting the stratum corneum prior to applying the dry formulation.

5. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 5/1/06 By: Diane E. Epperson